

K123952

510(k) Summary

for

MAR 20 2013

Sirona Dental Systems

CEREC Blocs C In

1 Sponsor

Sirona Dental Systems GmbH

Fabrikstrasse 31

D-64625 Bensheim

Germany

Contact Person: Fritz Kolle

Telephone: +49 6251 16 3294

Date Prepared: December 20, 2012

2 Device Name

Proprietary Name: CEREC Blocs C In

Common/Usual Name: Powder, Porcelain

Classification Name: Porcelain powder for clinical use

3 Device Classification

21 CFR 872.6660, Product Code EIH

4 Predicate Devices

Vita's Vitablocs® (K090644) and Wieland Dental + Technik's Press X Zr (K070772)

5 Intended Use

Fabrication of Dental restorations using Sirona Dental CAD/CAM System.

6 Indications for Use

CEREC Blocs C In are indicated for the production of crowns and veneers using Sirona CAD/CAM system.

7 Device Description

CEREC Blocs C In is an industrially manufactured, silicate glass ceramic block used to produce crowns and veneer. The block consists of an inlying, highly-chromatic dentine core and an overlying translucent enamel layer. It is grinded to custom made dental restorations using Sirona CAD/CAM systems. The block is initially manufactured in a sintered state; then, is individually processed to specification. One end plane of a block is mounted to a metal carrier that is inserted in the spindle's clamping chuck of the grinding machine.

CEREC Blocs C In are available in several colors and additional bleach color. The dental restorations obtain their individual color appearance by stain and glaze firing.

8 Scientific Concept

The underlying scientific concept is

- Processing dental restorations by Sirona Dental CAD/CAM System
- Restorations are grinded from an CEREC C In by a Sirona CAM machine

9 Physical and Performance Characteristics

9.1 Design

The design of the CEREC Blocs C In is described in section 7, Device Description.

9.2 Material Used

CEREC C In ceramics constitute blocks comprised of silicate glass ceramic. One end plane of a block is mounted to a metal carrier that is inserted in the spindle's

clamping chuck of the grinding machine. The material is biocompatible according to ISO 10993-1: 2009, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process".

9.3 Physical Properties

Final technical data of CEREC C In:

Properties	Value
Coefficient of thermal expansion CTE (20 – 500 °C)	$(9.3 \pm 0.3)10^{-6} \text{ K}^{-1}$
Density	2.36 g/cm ³
Bending strength (ISO 6872)	123 ± 18 MPa
Transformation range	620 ± 20 °C

9.4 Chemical Properties

Component	% of Total Weight
SiO ₂	55 - 65
Al ₂ O ₃	17 - 24
Na ₂ O	5 - 9
K ₂ O	7 - 11
B ₂ O ₃	0 - 2

Oxides, contained in very low concentrations and used e.g. for coloring, are not specified here.

10 Summary of the technological characteristics

Sirona CEREC C In and Wieland Dental + Technik's Press X Zr are made of silicate glass ceramic. Chemical properties are similar. Sirona CEREC C In and Vita's Vitablocs® are block shaped. All devices meet the ISO 6872: 2008, "Dentistry -- Ceramic materials". Physical properties are similar for all devices.

11 Nonclinical Testing

Bending strength tests have been performed.

12 Clinical Testing

Clinical tests have not been performed.

13 Conclusion

Based on the overall comparison of indications for use, contra-indications, material properties and processing/fabrication, Sirona Dental Systems believes that the CEREC blocs C In are substantially equivalent to Vita's Vitablocs® (K090644) and Wieland Dental + Technik's Press X Zr (K070772).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Mr. Fritz Kolle
Sirona Dental Systems GmbH
Fabrikstrasse 31
Bensheim, Germany D-64625

Re: K123952

Trade/Device Name: CEREC Blocs C In
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 20, 2012
Received: December 21, 2012

Dear Mr. Kolle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123952

Device Name: CEREC Blocs C In

Indications for Use:

CEREC blocs C In are indicated for the fabrication of veneers and of crowns in anterior teeth and in premolars that have not been endodontically treated, using the Sirona CAD/CAM system.

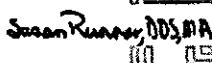
Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 Mary S. Runner -S
Susan Runner, DDS, MA 2013:03:19
13:53:46 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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